SUPPORTING STATEMENT FOR
MEDICAL DEVICES; THIRD-PARTY REVIEW UNDER THE U.S./E.C. MRA

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

The third-party program under the U.S./EC MRA is intended to implement that part of the U.S./EC MRA that covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices. Under the MRA, firms may apply to become designated as a U.S. CAB. Firms who are designated will be qualified to conduct quality system evaluations for all classes of devices and product type examinations and verifications for selected devices based on EC requirements under the voluntary third party program authorized by the MRA. Firms designated as EC CABs could conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA requirements. Under the voluntary third party program, reports of these evaluations would be submitted by the EC CABs to FDA. The EC CABs would also be required to maintain copies of their evaluation reports.

FDA requests approval of the following information collection:

Requests for designation as United States (U.S.) Conformity Assessment Bodies (CABs) - Under this program, U.S. companies may apply for designation as a U.S. CAB. Such designation will enable the company to perform third party reviews of U.S. products for export to the EC.

Premarket reports by European Community (E.C.) CABs - Under this program, EC CABs will be able to perform third party evaluations for certain products manufactured in Europe for export to the U.S. Third party evaluation is elective and at the discretion of the manufacturer of the product.

Quality system reports by E.C. CABs - Under this program, EC CABs will be able to perform third party audits of the quality systems established by manufacturers of European products manufactured for export to the U.S. Third party audit of quality systems is elective and at the discretion of the manufacturer of the product.

Recordkeeping

EC CABs must maintain records of their third-party evaluations of quality systems and premarket submissions for certain products manufactured for export to the U.S. for a period of no less than 3 years.

On July 2, 1998, FDA issued 3 notices: a notice of implementation (Tab A) of a third-party review program under the U.S./E.C. Mutual Recognition Agreement (MRA), A notice of availibility (Tab B) of a guidance document (Tab C) describing the program, and a notice announcing that FDA had requested emergency processing of a request for approval of the information collection requirements in the program under the Paperwork Reduction Act of 1995)). The program will implement that part of the U.S./E.C. MRA that covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices. Under the MRA, individuals may apply for nomination as a U.S. CAB who would conduct quality system evaluations for all classes of devices and product type examinations and verifications for selected devices based on EC requirements. EC CABs could conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA requirements, and must submit review reports to FDA.

The FDA is now seeking approval for the collection of such information.

2. By Whom and for What Purpose the Information is to be Used

Information from these information collection provisions will be used to implement that part of the Medical Device Annex that covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices.

3. Consideration of Information Technology

This program allows alternative appropriate technology. Applications and reports can be electronically submitted if the format is approved by FDA.

4. Efforts to Identify Duplication and Similar Information Already Available

Assessment of prospective U.S. CABs for purposes of conducting quality system evaluations and product type testing and verifications will be conducted under the National Voluntary Conformity Assessment System Evaluation (NVCASE) administered by the National Institute of Standards and Technology (NIST) of the U.S. Department of Commerce. The FDA is the only Federal agency responsible for the collection of quality system evaluation reports and premarket evaluation reports for medical devices. Therefore, duplication with other data sources is nonexistent.

5. Small Businesses

Participation in the third-party program is entirely voluntary. As such, there is potentially no impact on small businesses unless they elect to participate in the program.

FDA aids small business by providing guidance and information through the Division of Small Manufacturers Assistance (DSMA) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DSMA provides workshops, on-site evaluations and other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device establishment and listing requirements. The Division also maintains a toll-free "800" telephone number which firms may use to obtain regulatory compliance information.

6. Consequences of Less Frequent Information Collection and Technical or Legal Obstacles.

There is no established frequency for the information collection under the third-party review program.

7. Consistency with the Guidelines in 5 CFR 1320.5

This regulation is consistent with principles in 5 CFR 1320.5.

8. Consultation Outside the Agency

In the notice announcing that FDA was requesting emergency processing of its application for approval of the information collection requirements in the program, FDA provided an opportunity for interested persons to submit written comments on the information collection requirements. FDA received 2 comments.

One comment questioned why FDA chose 12 as the number of U.S. CABs, when Europe already has 20. FDA made its estimate based on the number of organizations that have expressed an interest to FDA in becoming CABS and FDA still believes that 12 is the appropriate number.

The other comment questioned why FDA did not include all eligible class I and class II devices in the program. FDA did not include in the program 3 class I devices that are regulated by the Center for Biologics Evaluation and Research (CBER), because FDA determined that it would not be cost effective to train CBER employees in the program for only 3 devices. FDA included in the program the 97 class II for which guidance and/or recognized standards exist and which represent 60% of the 510(k)s we receive each year. If the program is successful, FDA will add additional devices, as appropriate.

9. Payments or Gifts to Respondents

No payment or gifts shall be provided to respondents under this regulation.

10. Confidentiality of Information

Information regarding U.S. CABs, and review reports by E.C. CABs are available under the Freedom of Information Act and 21 CFR Part 20.

11. Sensitive Questions

The information collection does not include questions concerning sex, behavior, attitudes, religious beliefs, or private matters.

12. Estimates of Burden Hours and Explanation

The following is a summary of the estimated annual burden hours for participation in the voluntary program:

ESTIMATED ANNUAL BURDEN FOR REPORTING

| *ITEM* | *NUMBER OF RESPDTS* | *NUMBER RESPONSES PER RESPDT* | *TOTAL ANNUAL RESPONSES* | *HOURS/ RESPDT* | *TOTAL HOURS* |
|---|---|---|---|---|---|
| Requests for Designation as U.S. CAB | 12 | 1 | 12 | 24 | 288 |
| Premarket Reports by EC CABs | 20 | 5 | 100 | 40 | 4,000 |
| Quality System Reports by EC CABs | 20 | 5 | 100 | 32 | 3,200 |
| | | | | | 7,488 |

There are no capital costs or operating and maintenance costs associated with this information collection.

ESTIMATED ANNUAL RECORDKEEPING BURDEN

| *ITEM* | *Number of Record-keepers* | *Annual Frequency per Recordkeeping* | *Total Annual Records* | *Hours/ Recordkeeper* | *Total Hours* |
|---|---|---|---|---|---|
| Premarket Reports by EC CABs | 5 | 20 | 100 | 10 | 1000 |
| Quality System Reports by EC CABs | 5 | 20 | 100 | 10 | 1000 |
| | | | | | 2000 |

There are no capital costs or operating and maintenance costs associated with this information collection.

The following is an explanation of the burden estimate:

**Reporting Burden:**

**Requests for designation as U.S. CAB.** Under this program, U.S. firms may apply for designation as a U.S. CAB. Such designation will enable that firm to perform third party evaluations of U.S. products for export to the EC. Likewise, European firms may apply to be designated as EC CABs, which will enable them to perform third party reviews of products to be exported to the U.S. . The application for nomination as an EC CAB does not represent a paperwork burden subject to the PRA because the designation procedure is an internal process which is required by, and administered by, European authorities. Only the application for designation as a U.S. CAB represents a paperwork burden under the PRA. The agency anticipates, based on discussions with NIST and officials of other standards organizations, that it will receive approximately 12 applications for designation as U.S. CABs.

**Premarket reports.** Under this program, EC CABs will be able to perform third party evaluations for certain products produced in Europe for export to the U.S. EC CABs would be required to submit to FDA reports of their evaluations. Based upon information gathered during the negotiation of the U.S./EC MRA, the agency anticipates that European manufacturers will request third party review for approximately 100 medical device products annually. The agency further estimates, based on dialogue with EC. officials, that 20 firms will be designated to act as

EC CABs.

**Quality system reports.** Under this program, EC CABs will be able to perform third party evaluations of the quality systems established by manufacturers of European products produced for export to the U.S. . EC CABs would be required to submit to FDA reports of their evaluations. Based upon information gathered during the negotiation of the U.S./EC MRA, the agency anticipates that European manufacturers will request third party audits for approximately 100 medical device products annually. The agency estimates that 20 EC CABs will perform these evaluations.

**Recordkeeping**

As stated above, firms designated as EC CABs will be able to perform third party evaluations of quality systems and premarket submissions for certain products produced for export to the U.S. Such review will be conducted consistent with FDA regulatory requirements, and FDA will require the reviewers to keep, in their records, a copy of the report that they submit to FDA for each review. The agency anticipates that 100 premarket reports and 100 quality system reports will be generated and required to be maintained by EC CABs annually. The agency estimates that 100 records of review of quality systems and premarket submissions will be retained by the designated reviewers. The agency further estimates that each reviewer will require no more than 10 hours (2 hours per recordkeeping per report) for each to maintain such records annually.

**Costs to Respondents:** There are no costs imposed by this program, as it is a voluntary program intended to provide manufacturers with an alternative path of review. The cost of conducting evaluations and submitting reports will be charged by the E.C. CABs to manufacturers who choose to participate in the program, but such cost is not established by the program requirements.

13. Annual Costs to Respondents

No capital or operational expenses are expected as a result of this proposal.

14. Government Costs:

Costs to the government is limited to the time required to review applications for designation as U.S. CABs. This will be done under the under the NVCASE program administered by NIST of the U.S. Department of Commerce. The NVCASE program is already operational and the applications for designation as U.S. CABs would not create a significant change in the workload.

15. Changes in Burden

There is no change in burden.

16. Statistical Reporting

No publication of information for statistical use is planned.

17. Exemption for Display of Effective Date

FDA is not seeking an exemption of display of effective date.

18. Exception to Certification Statement

There are no exceptions to the certification statement identified in Item 19 of OMB Form 83-I.

List of Attachments:
Tab A - Notice of Implementation of Third Party Review Program Under the U.S./E.C. MRA

Tab B - Notice of Availability of Guidance

Tab C - Guidance for Implementation of Third Party Review Program Under the U.S./E.C. MRA
21 CFR Part 803